



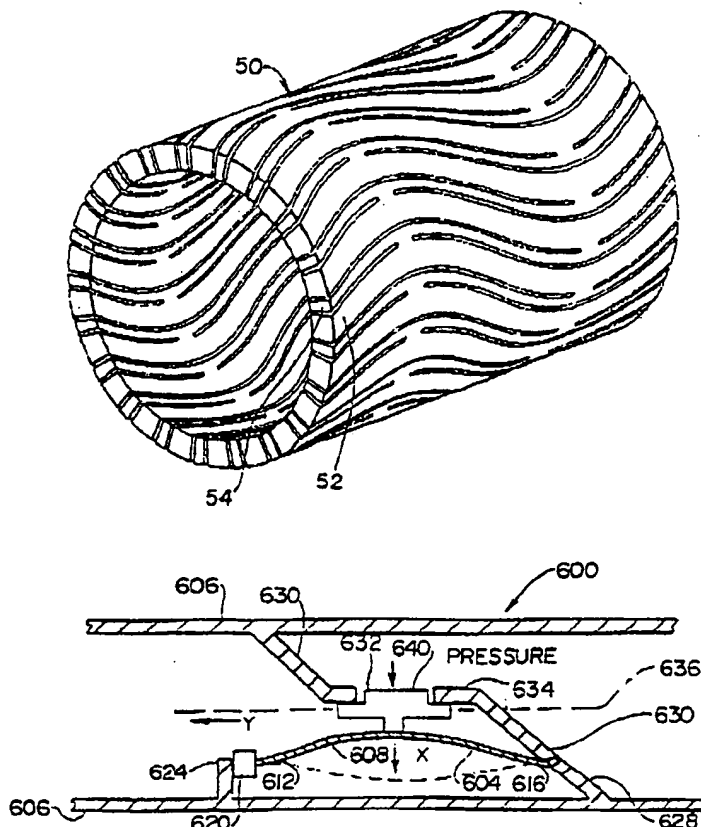
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/06, A61B 17/11, A61F 2/00, F16K 31/00		A3	(11) International Publication Number: WO 98/32412
			(43) International Publication Date: 30 July 1998 (30.07.98)
(21) International Application Number: PCT/US98/01310 (22) International Filing Date: 23 January 1998 (23.01.98) (30) Priority Data: 60/036,359 24 January 1997 (24.01.97) US (71) Applicant (for all designated States except US): SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311-1566 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): BESSELINK, Petrus, Anto- nius [NL/NL]; Gronausestraat 1220, NL-7534 AT Enschede (NL). (74) Agents: ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343-9131 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> (88) Date of publication of the international search report: 12 November 1998 (12.11.98)	

(54) Title: BISTABLE SPRING CONSTRUCTION FOR A STENT AND OTHER MEDICAL APPARATUS

(57) Abstract

The present invention is directed to bistable cells and their use in devices, particularly medical devices such as stents, clamps and valves. An expandable stent formed of a plurality of bistable cells is described. The stent has two or more stable configurations, including a first stable configuration with a first diameter and a second stable configuration with a second, larger diameter. A valve comprising a bistable cell for use in eliminating incontinence is also disclosed.



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INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06 A61B17/11 A61F2/00 F16K31/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B F16K F16L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 18359 A (FOUERE) 20 June 1996 see abstract; figures 1,2 ---	1,11-13, 17-21, 28-33
X	WO 95 09584 A (GUERBET) 13 April 1995	1,11-13, 21, 28-33, 55-57
Y	see page 9, line 26 - page 10, line 12; figures ---	58
X	WO 96 09013 A (WAKE FOREST INIVERSITY) 28 March 1996 see abstract; figures 10,14 ---	1,11-13, 30-33
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

4 September 1998

Date of mailing of the international search report

16.09.98

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 562 690 A (GREEN ET AL) 8 October 1996	1, 54
A	see column 5, line 36 - column 7, line 13; figures 1-8	7, 8
P, X	US 5 695 516 A (FISCHELL ET AL.) 9 December 1997	1, 9, 11-13, 15, 16, 28-33
A	see the whole document	2-4
P, X	WO 97 04721 A (MEDSTENT) 13 February 1997	1, 4, 11-13, 28-33
	see page 7, line 3 - line 33; figures 1, 3, 8-10	
Y	EP 0 587 197 A (ANGIOMED) 16 March 1994 see claim 7	58
A	US 5 234 448 A (WHOLEY ET AL.) 10 August 1993 see the whole document	7, 8, 54
A	WO 95 31945 A (SCIMED LIFE SYSTEMS) 30 November 1995	6
A	EP 0 326 426 A (JAPAN MEDICAL SUPPLY) 2 August 1989	
X	WO 96 41589 A (COOK WILLIAM EUROP; KAVTELADZE ZAZA ALEXANDROVICH (RU); KORSHOK AL) 27 December 1996 see page 16, line 10 - line 35; figures	51
A		37-39, 41-43, 46, 47
X	WO 93 22986 A (SCHNEIDER USA INC) 25 November 1993 see page 13, line 16 - line 26	51
A		37-42, 47
A	EP 0 688 545 A (TERUMO CORP) 27 December 1995 see abstract; figures	37-39, 41-43, 45, 47, 65
A	EP 0 364 787 A (EXPANDABLE GRAFTS PARTNERSHIP) 25 April 1990 see column 1, line 25 - line 50; figures	37-39, 65
	-/--	

INTERNATIONAL SEARCH REPORT

In: International Application No

PCT/US 98/01310

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 664 107 A (NAZARI STEFANO) 26 July 1995 see column 3, line 44 - column 4, line 37; figures	52
X	US 4 994 071 A (MACGREGOR DAVID C) 19 February 1991 see column 3, line 54 - column 4, line 18; figures	52
X	GB 2 081 173 A (BEHAR YVES; ALBERTINI PROSPER JEAN; GEFFROY JEAN LOUIS) 17 February 1982 see abstract; figures	52
A	US 3 508 587 A (MAUCH HANS A) 28 April 1970 see column 3, line 6 - line 48; figure 2A	52, 53
X	EP 0 734 698 A (VARIOMED AG) 2 October 1996 see the whole document	59
A	EP 0 679 372 A (ADVANCED CARDIOVASCULAR SYSTEM) 2 November 1995 see figures	59
A	WO 96 03942 A (RAM MICHAEL J ; KALB IRVIN M (US); SHAW ROBERT H (US)) 15 February 1996 see page 10, line 14 - page 11, line 14; figures	66, 67, 70, 71
A	FR 2 642 812 A (CROUZET SA) 10 August 1990 see abstract; figures	66-68
A	EP 0 636 345 A (SENTINEL MEDICAL INC) 1 February 1995 see abstract; figures	66, 70, 71
A	US 3 069 125 A (J.C. HEWITT, JR.) 18 December 1962 see the whole document	66, 68, 69
X	WO 96 29028 A (GRASS ANTHONY JAMES ; UNIV LONDON (GB); ADISESHIAH MOHAN (GB)) 26 September 1996 see page 3, paragraph 1 - paragraph 3; figures	73, 74
A	see page 6, last paragraph - page 7, paragraph 2	75
X	EP 0 744 164 A (COOK INC) 27 November 1996 see column 6, line 15 - line 37; figures	73, 74
A	see column 12, line 36 - line 42	75
	-/--	

INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 169 515 A (LIFELINE LTD) 16 July 1986 see the whole document	73
A	---	74,75
X	EP 0 421 729 A (MEDTRONIC INC) 10 April 1991 see abstract; figures	73,74
A	---	
A	US 5 141 360 A (ZEMAN DAVID) 25 August 1992 see column 5, line 34 - line 68; figure 3	73-76
A	---	
A	WO 95 32757 A (NITINOL MEDICAL TECHNOLOGIES I) 7 December 1995 see abstract; figures	73-76

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/01310

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 48-50 60-64 72
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
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because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
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Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 98/01310

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-36, 54-58

A medical device containing at least one unit cell with one relatively flexible segment and one relatively rigid segment

1.1 Claims 1,2,5-29

A unit cell with symmetrical load-displacement

1.2 Claims 1,3,5-29

A unit cell with asymmetrical load-displacement characteristic, most stable in expanded state

1.3 Claims 1,4-29

A unit cell with asymmetrical load-displacement characteristic, most stable in collapsed state

1.4 Claims 30-36

A medical device with a multistable spring system

1.5 Claim 1,54

A clamp

1.6 Claims 55-58

A graft stent with expansion rings

2. Claims: 37-47,65

A stent with a negativ spring constant

3. Claim : 51

A stent with a plurality of diameters

4. Claims: 52, 53

An expandable device

5. Claim : 59

A stent with wavelike members

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 98/01310

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

6. Claims: 66-71

A bistable valve

7. Claims: 73-77

A medical device with a cell with four rigid segments

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Patent Application No

PCT/US 98/01310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9618359 A	20-06-1996	FR 2728156 A AU 4119896 A EP 0843538 A	21-06-1996 03-07-1996 27-05-1998
WO 9509584 A	13-04-1995	FR 2710834 A AT 162065 T AU 7858594 A CA 2173500 A DE 69407984 D DE 69407984 T EP 0722304 A ES 2115262 T JP 9503141 T	14-04-1995 15-01-1998 01-05-1995 13-04-1995 19-02-1998 03-09-1998 24-07-1996 16-06-1998 31-03-1997
WO 9609013 A	28-03-1996	US 5702419 A AU 3418395 A CA 2200489 A	30-12-1997 09-04-1996 28-03-1996
US 5562690 A	08-10-1996	NONE	
US 5695516 A	09-12-1997	NONE	
WO 9704721 A	13-02-1997	AU 6511196 A EP 0840578 A NO 980302 A PL 324781 A US 5776181 A	26-02-1997 13-05-1998 24-03-1998 08-06-1998 07-07-1998
EP 587197 A	16-03-1994	DE 9014230 U AT 107495 T DE 9116936 U DE 59102001 D DK 481365 T EP 0481365 A ES 2057709 T JP 4256759 A	21-11-1991 15-07-1994 01-09-1994 28-07-1994 07-11-1994 22-04-1992 16-10-1994 11-09-1992
US 5234448 A	10-08-1993	AT 156986 T CA 2090763 A,C CA 2173636 A	15-09-1997 29-08-1993 29-08-1993

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/01310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5234448 A		DE 69313162 D	25-09-1997
		EP 0558352 A	01-09-1993
		EP 0781528 A	02-07-1997
		US 5254127 A	19-10-1993
WO 9531945 A	30-11-1995	CA 2190012 A	30-11-1995
		EP 0759730 A	05-03-1997
		JP 10500595 T	20-01-1998
EP 326426 A	02-08-1989	JP 1192367 A	02-08-1989
		JP 2561853 B	11-12-1996
		CA 1307885 A	29-09-1992
		DE 68920055 D	02-02-1995
		DE 68920055 T	11-05-1995
		US 4950258 A	21-08-1990
WO 9641589 A	27-12-1996	AU 6121896 A	09-01-1997
		EP 0836450 A	22-04-1998
WO 9322986 A	25-11-1993	AU 693054 B	18-06-1998
		AU 1905397 A	19-06-1997
		AU 678350 B	29-05-1997
		AU 3789793 A	13-12-1993
		CA 2134090 A,C	25-11-1993
		CA 2179668 A	09-11-1993
		DE 9390115 U	22-12-1994
		EP 0639958 A	01-03-1995
		JP 2660101 B	08-10-1997
		JP 7502673 T	23-03-1995
		US 5645559 A	08-07-1997
EP 0688545 A	27-12-1995	JP 8000738 A	09-01-1996
		JP 8196642 A	06-08-1996
		JP 8215318 A	27-08-1996
EP 0364787 A	25-04-1990	AU 623438 B	14-05-1992
		AU 4248589 A	12-04-1990
		CA 1322628 A	05-10-1993
		GR 3003987 T	16-03-1993
		JP 2174859 A	06-07-1990

INTERNATIONAL SEARCH REPORT

Information on patent family members

In International Application No

PCT/US 98/01310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0364787 A		JP 2680901 B	19-11-1997
		US 5195984 A	23-03-1993
EP 0664107 A	26-07-1995	IT 1269443 B	01-04-1997
		US 5554183 A	10-09-1996
US 4994071 A	19-02-1991	NONE	
GB 2081173 A	17-02-1982	FR 2487086 A	22-01-1982
		DE 3127446 A	06-05-1982
		JP 57052015 A	27-03-1982
US 3508587 A	28-04-1970	NONE	
EP 0734698 A	02-10-1996	DE 19512066 A	28-11-1996
		DE 19540851 A	07-05-1997
		AT 169484 T	15-08-1998
		DE 19516191 A	06-02-1997
		JP 9010318 A	14-01-1997
EP 0679372 A	02-11-1995	CA 2147709 A	26-10-1995
		JP 8126704 A	21-05-1996
		US 5725572 A	10-03-1998
WO 9603942 A	15-02-1996	US 5476434 A	19-12-1995
		AU 3320695 A	04-03-1996
		CA 2195949 A	15-02-1996
		CN 1159155 A	10-09-1997
		EP 0793465 A	10-09-1997
		JP 10507652 T	28-07-1998
		US 5509889 A	23-04-1996
		US 5704353 A	06-01-1998
FR 2642812 A	10-08-1990	NONE	
EP 0636345 A	01-02-1995	AU 677061 B	10-04-1997
		AU 6746894 A	02-02-1995
		CA 2127637 A	27-01-1995
		JP 7313520 A	05-12-1995
		US 5562692 A	08-10-1996

INTERNATIONAL SEARCH REPORT

Information on patent family members

In tional Application No

PCT/US 98/01310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0636345 A		US 5735815 A	07-04-1998
US 3069125 A	18-12-1962	NONE	
WO 9629028 A	26-09-1996	AU 5116896 A	08-10-1996
		CA 2216522 A	26-09-1996
		EP 0817599 A	14-01-1998
EP 0744164 A	27-11-1996	AU 5240596 A	19-12-1996
		CA 2176987 A	26-11-1996
		JP 9099095 A	15-04-1997
		US 5707376 A	13-01-1998
GB 2169515 A	16-07-1986	NONE	
EP 0421729 A	10-04-1991	CA 2026604 A	03-04-1991
		DE 69024901 D	29-02-1996
		DE 69024901 T	14-08-1996
		IE 73670 B	02-07-1997
		JP 3151983 A	28-06-1991
US 5141360 A	25-08-1992	US 5292073 A	08-03-1994
		US 5263791 A	23-11-1993
		US 5224796 A	06-07-1993
WO 9532757 A	07-12-1995	US 5540712 A	30-07-1996
		CA 2191307 A	07-12-1995
		EP 0788390 A	13-08-1997
		JP 10504200 T	28-04-1998
		US 5746765 A	05-05-1998